



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 01-597)

In the Application of:

Garthwaite, et al.

Serial No.: 09/854/264

Filed: May 11, 2001

For: Alodsterone Antagonist Composition For  
Release During Aldosterone Acrophase

Art Unit: 161

Examiner: Todd

PATENT

TECH CENTER 1600/2800

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BOX IDS  
Commissioner for Patents  
Washington, D.C. 20231

TRANSMITTAL LETTER

In regard to the above identified application:

1. We are transmitting herewith the attached:
  - a. Information Disclosure Statement (IDS) (2 sheets);
  - b. Form PTO-1449 (2 sheets);
  - c. International Search Report;
  - d. 15 Cited References; and
  - e. Return Receipt Postcard.
2. With respect to fees:
  - a. A check in the amount of \$180.00 is enclosed.
3. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2490.
4. CERTIFICATE OF MAILING UNDER 37 CFR § 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described in paragraph 1 hereinabove, are being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Box IDS, Commissioner for Patents, Washington, D.C. 20231 on January 7, 2003.

By:

Steven J. Sarrusi  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Case No. 01-597)

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TECH CENTER 1600/2900

In the Application of:

Garthwaite, et al.

Serial No.: 09/854/264

Filed: May 11, 2001

For: Alodsterone Antagonist Composition For  
Release During Aldosterone Acrophase

Art Unit: 1615

Examiner: Todd Ware

**INFORMATION DISCLOSURE STATEMENT**

**BOX IDS**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. Section 1.97 - 1.99, the Applicant wishes to make the following references of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56. Copies of the references cited below are enclosed. These references are also listed on the enclosed PTO Form 1449.

In the judgment of the undersigned, portions of the listed references may be material to the Examiner's consideration of the presently pending claims. However, the references have not been reviewed in sufficient detail to make any other representation and, in particular, no representation is intended as to the relative relevance between references, whether cited in this or prior statements. This statement is not a representation that the listed references have effective dates early enough to be "prior art" within the meaning of 35 U.S.C. Section 102 or Section 103.

**United States Patents**

1. Cella, et al., U.S. Patent No. 3,013,012, issued December 12, 1961.
2. Grob et al., U.S. Patent No. 4,559,332, issued December 17, 1985.
3. Barnwell, U.S. Patent No. 5,391,377, issued February 21, 1995.

### Foreign Documents

4. PCT Patent Publication No. WO 95/15166, published June 8, 1995.
5. PCT Patent Publication No. WO 96/40255, published December 19, 1996.
6. PCT Patent Publication No. WO 96/40257, published December 19, 1996.
7. PCT Patent Publication No. WO 98/25948, published June 18, 1998.
8. PCT Patent Publication No. WO 99/29136, published June 10, 1999.
9. PCT Patent Publication No. WO 00/33847, published June 15, 2000.

### Other Documents

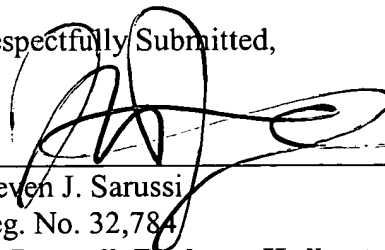
10. Cugini et al. (1985), *Maturitas*, 7:175-186.
11. Cugini et al. (1982), *Chronobiologia*, 12:155-165.
12. De Gasparo et al. (1989), *Journal of Steroid Biochemistry*, 32(13):223-227.
13. Kawasaki et al. (1990), *Horm. Metab. Res.*, 22:636-639.
14. Koopman et al., (1985), *Neth. J. Med.*, 28:416-423.
15. Richards et al., (1987), *Clinical Science*, 73:489-495.

In accordance with MPEP Sections 609 and 707.05(b), it is requested the document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

Date: January 7, 2003

By:

Respectfully Submitted,



Steven J. Sarussi

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